Opening Statement for the Honorable Brett Guthrie
"Evaluating Approaches to Diagnostic Test Regulation and the Impact of the FDA's Proposed Rule."
March 21, 2024

- Thank you to our witnesses for joining us today. We are here to examine the history of diagnostic test regulation, previous legislative proposals to update this regulatory framework, and the Biden administration's current proposal to regulate laboratory developed tests, or LDTs, as medical devices.

- The current oversight structure for diagnostic tests, including lab-developed tests, is split between the U.S. Food and Drug Administration and the Centers for Medicare and Medicaid Services. In 1976, Congress gave the FDA the explicit authority to regulate the medical device industry. At the time of enactment, the FDA adopted an enforcement discretion policy as a matter of practice over LDTs.

- Over time, it became clearer to policymakers, industry stakeholders, and patient groups that a separate regulatory approach was needed for LDTs to protect the health and well-being of patients as well as create more standardization across the health care system, which led to the passage of the 1988 Clinical Laboratory Improvement Amendments. In establishing the CLIA program, Congress intended to ensure the accuracy and reliability of all laboratory testing in the wake of reports of inaccurate clinical tests.

- LDTs are viewed as important tools from medical uses from helping to treat cancer to common public health purposes like helping law enforcement and health care professionals determine which drugs are being trafficked and sold in their community.

- Lab developed tests also must go through certification requirements under CLIA in addition to state public health regulators, and independent accrediting agencies, such as Dr. Karcher's organization, the College of American Pathologists, or CAP.

- Despite many known benefits of lab developed tests, the FDA has repeatedly attempted, for almost two decades, to completely reform how these tests are regulated in order to give the agency sole discretion and policing power over all diagnostic tests, regardless of whether they are developed and run by the same laboratory or developed to be sold and used elsewhere.

- Under a proposed FDA rule announced in September 2023, the vast majority of LDTs will be regulated as medical devices. This means they would need to go through FDA's existing medical device framework, such as the 510K approval process or premarket approval. Labs would not be able to make simple modifications to existing diagnostic tests or even novel tests, undermining the flexibility provided through LDTs.

- Even more problematic, the proposed rule doesn't include a grandfathering clause that would allow for the continued use of CLIA certified LDTs without disruption.

- Commissioner Califf cited concerns relating to the performance of current LDTs that could potentially lead to unnecessary care or delaying necessary care as a primary reason why the FDA needs this additional policing power. He further states that over 70% of medical conditions rely on LDTs, and other senior FDA officials have stated the current approach disincentives innovation as conventional kit manufacturers do adhere to the medical device framework.

- To be clear, I agree with Commissioner Califf that our regulatory approach always needs to ensure we're protecting patients while facilitating innovation. However, I remain concerned whether FDA's proposal will protect patients in the most effective way, achieve lower costs, or foster greater innovation.

- However, we cannot overlook the unintended consequences this proposed rule could cause. Namely, it could lead to greater consolidation amongst testing providers, reduced access to high-quality care for patients living with life-threatening diseases, especially in the cell and gene therapy space, set our health care system back on our mission to move closer toward personalized medicine, and have harmful effects on disadvantaged and rural populations.

- I also question whether the FDA is going to execute the authorities that it seeks given its experience with an influx of Covid applications.

- To put all of this into greater context, the American Hospital Association's comment letter, one of nearly 7,000 the FDA received on this proposed rule, mentions one of its systems has 1,600 lab-developed tests. Assuming they were pursuing a 510K approval, the 2023 user fee rates paid by manufacturers to the FDA for a 510K this could mean that system ends up paying upwards of more than $31 million to comply with the FDA's rule.

- As diagnostic testing becomes more complex, I believe it is essential that Congress work with the public health community, physicians, and patient groups to address any current challenges with providing patients with the highest-quality diagnostics without stifling innovation.

- I cannot support the FDA's proposed rule and hope it is withdrawn but do look forward to continuing the discussion on possible legislative proposals to address outstanding challenges with LDTs.

- Thank you, I yield back.